

Remarks

Claims 1-3, 5-7, 9-10, 12-15 and 17-19 are currently pending in this application, each of which have been rejected under 35 U.S.C. § 102(b) in view of U.S. Patent No. 6,041,260 to Stern ("Stern"). Applicant respectfully disagrees with the Examiner's rejection, but has amended independent claims 1 and 15 to further clarify distinguishing features.

Stern discloses an endometrial ablation device through which RF current "is passed through the entire surface area of an endometrium in order to provide heating of the endometrium." Abstract, lines 3-5. In other words, the device of Stern depends on, and must have, *direct or indirect contact* with the endometrial lining in order to complete the electrical circuit and cause ablation. This is further described at Col. 4, line 7-9, stating "radio frequency electric current passes through the dilated endometrial surface for a time sufficient to destroy the endometrial cells." It is the "electric current flowing **through the tissue** [that] causes resistive heating." Col. 4, lines 29-30. Absent such contact, there is no electrical pathway and no heating. Thus, for any of the multiple electrodes relied on by Stern to deliver this RF energy, if such electrode is not in direct contact with the endometrial lining, ablation will not occur at that specific location leading to less than complete ablation coverage. Given the non-uniformity of the uterine cavity, this is almost certain to occur in at least some areas, thus devices of this type often require conductive gels or coatings to improve coverage. Col. 5, lines 6-23. This deficiency and disadvantage of devices such as those disclosed by Stern, is outlined in the background of the present specification (See p. 2, lines 6-9).

The present invention, to the contrary, does not rely on any contact with the lining of the body cavity to be ablated in order to generate ablative heat. Claims 1 and 15 have been amended to clearly recite a resistive heating element(s) that is coupled with the voltage source "so as to form a closed circuit in the absence of *direct or indirect contact with any body fluid or tissue*", and emits resistive heat "*through the flexible resistive heating element itself*" when so coupled. These features enable the device to provide full and substantially uniform coverage in the area(s) covered by the resistive elements, regardless of any irregularities in the

shape or contour of the endometrium. These amendments to claim 1 have been reproduced below:

at least one flexible resistive heating element coupled to the distendable bladder, the resistive heating element being electrically coupleable to a voltage source so as to form a closed circuit in the absence of direct or indirect contact with any body fluid or tissue, and emitting resistive heat through the flexible resistive heating element itself when so coupled . . .

Referring back to Stern as compared to newly amended independent claims 1 and 15, Stern fails to teach or suggest a flexible resistive heating element electrically coupled to a voltage source *so as to form a closed circuit in the absence of direct or indirect contact with any body fluid or tissue*, as is now specifically recited. Stern further fails to teach or suggest a device having such a resistive heating element that, when so coupled, emits resistive heat *through the flexible heating element itself* as opposed to requiring coupling with body tissue or fluid to be the source of any such resistive heat. Thus, as Stern fails to teach or suggest elements present in amended claims 1 and 15, applicants respectfully submit that Stern does not anticipate these claims, or any of claims 2-3, 5-7, 9-10, 12-14 or 17-19 which depend therefrom. Reconsideration and allowance of all pending claims is respectfully requested.

Applicants believe that no fee is due in connection with this response. The Commissioner is hereby authorized, however, to charge any additional fees that may be required to Account No. 10-0750/GYN-5011/MJS. This Authorization is being submitted in triplicate.

Respectfully submitted,
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